IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

CHRISTOPHER ATWOOD
3399 Ky. 910
Liberty, KY 42539

And

REBEKAH BRADY
212 Locust Avenue
Florence, KY 41042

And

JENNIFER HICKEY
8783 Richmond Road
Union, KY 41091

And

ROBERT & MELAINE HOUGHTON
413 Barkley Street
Falmouth KY, 41040

And

PAUL MARKSBERRY, JR
1211 Garrard St.
Covington, KY 41011

And

HIRAM & DAWN MCCAULEY
3734 Autumn Road
Elsmere, KY 41018

And

CAROL ROSS
Po Box 636
Milan, Indiana 47031

And

Case No. A 1 6 0 2 5 3 7

JUDGE

COMPLAINT
& JURY DEMAND

(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER)

FILED
MAY - 2 2016
TRACY WINKLER
CLERK OF COURTS

MICHAEL & DIANE SANDER
2014 Benton Road, Apt. B
Covington, KY 41011

And

DAVID & NANCY SHEMPERT
27 Chambers Avenue
Walton, KY 41094

And

RICHARD ALLEN STANFIELD
4258 Aspen Drive
Independence, KY 41051

Plaintiffs,

v.

ABUBAKAR ATIQ DURRANI, M.D.,
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail

And

CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail

And

WEST CHESTER HOSPITAL, LLC
7700 UNIVERSITY DRIVE
WEST CHESTER, OH 45069
SERVE: GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202
(Serve via Certified mail)

And :
:
UC HEALTH :
SERVE: GH&R BUSINESS SVCS., INC. :
511 WALNUT STREET :
1900 FIFTH THIRD CENTER :
CINCINNATI, OH 45202 :
(Serve via Certified mail) :
:
Defendants. :

Come now Plaintiffs, and file this Complaint and jury demand, pursuant to the agreement of the parties and Order of the Court, and state as follows:

INTRODUCTORY PARAGRAPH

1. All of the Plaintiffs filed in this lawsuit are residents of and domiciled in the State of Ohio.
2. **Plaintiffs have filed these cases together because of the common fact each of them had surgeries performed by Dr. Durrani while he was under suspension at West Chester Hospital.**
3. A memorandum, attached as **Exhibit A**, discusses conversations that Brian Isaacs and Santen Hughes Law firm had, which addresses and confirms that Dr. Durrani was suspended from August 6, 2010 through at least October 5, 2010 at West Chester Hospital. Exhibit B is the list of cases subject to this Complaint allegation.
4. The memorandum states, Dr. Durrani was suspended he was not allowed to schedule new patients or perform surgeries, etc.
5. Dr. Durrani, during his suspension from August 6, 2010 until October 5, 2010, performed surgeries on multiple Plaintiff's by labeling the surgeries "emergencies."
6. Dr. Durrani performed more than 30 surgeries while he was under suspension at West Chester Hospital.

7. Plaintiffs, Connie Underwood, Debbie Rodriguez, and Todd Ray, Mike Sander, Richard Stanfield, David Shempert, Hiram McCauley, Paul Marksberry, Robert Houghton, Jennifer Hickey, Rebekah Brady and Christopher Atwood all have Infuse/BMP-2 implanted in their spines from surgeries Dr. Durrani performed at West Chester Hospital/ UC Health.
8. Plaintiff, Carol Ross, had surgery at West Chester Hospital and during that surgery Dr. Durrani implanted PureGen into Plaintiff's spine.
9. Plaintiffs Connie Underwood, Debbie Rodriguez, and Todd Ray are also Plaintiffs that Dr. Durrani performed surgery on while he was under suspension at West Chester Hospital; however, these cases are already filed with this Court.
10. Plaintiff Faye Rosebery is also a Plaintiff that Dr. Durrani performed surgery on while he was under suspension at West Chester Hospital; however, this case has been filed in Butler County Court.
11. Additionally, these cases are being filed together to be cost efficient as well as being filed together for their common scheme of facts and based upon Judge Ruehlman's December 15 Court Order Plaintiffs will request ALL cases involving Dr. Durrani operating while suspended be tried together.

JURISDICTION AND VENUE

12. At all times relevant, Plaintiffs were residents of and domiciled in the State of Ohio.
13. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
14. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

15. At all times relevant, West Chester Hospital, LLC (hereinafter "West Chester Hospital"), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

16. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and which shared certain services, profits, and liabilities of hospitals including West Chester.

17. At all times relevant herein, West Chester Medical Center, Inc., aka West Chester Hospital held itself out to the public, and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.

18. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

19. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.

20. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC. UC Health is located in Hamilton County making Hamilton County appropriate to bring this lawsuit.

21. The amount in controversy exceeds the jurisdictional threshold of this Court.

22. These Plaintiffs cases have previously been dismissed pursuant to Civ. R. 41(A)(1)(a) and is now being refiled within the time allowed by O.R.C. 2305.19.

FACTUAL ALLEGATIONS OF PLAINTIFFS

CHRISTOPHER ATWOOD:

23. At all times relevant, Plaintiff Christopher Atwood, ("Plaintiff", or "Mr. Atwood") was a resident of and domiciled in the State of Kentucky.

24. In or around spring 2010, Mr. Atwood was experiencing moderate flank pain on his left side.

25. Mr. Atwood's was referred to Dr. Durrani.

26. In the spring of 2010, Mr. Atwood visited Dr. Durrani at CAST in Blue Ash.

27. Dr. Durrani recommended spinal injections and one session of physical therapy.

28. A short time after, Dr. Durrani recommended surgery.

29. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

30. Upon information and belief, Dr. Durrani, CAST, and West Chester never informed Plaintiff that Dr. Durrani's privileges were suspended.

31. On or about September 22, 2010, Dr. Durrani performed a T7-T12 fusion surgery on Plaintiff at West Chester Hospital, inserting 2 rods and 15 screws.

32. The September 22, 2010 surgery occurred during the time West Chester Hospital/ UC Health suspended Dr. Durrani's privileges.

33. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label" and/or Puregen without Plaintiff's knowledge or consent, causing Plaintiff harm.

34. The use of BMP-2 increases a person's chance of cancer by 3.5%

35. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

36. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

37. Plaintiff followed up with Jamie Moore at CAST.

38. Three weeks following the surgery, Plaintiff followed up with Dr. Durrani at CAST.

39. Plaintiff visited with Dr. Durrani every 6 months following surgery.

40. Plaintiff is now in worse pain than he was in prior to surgery with Dr. Durrani.

41. Plaintiff has lost flexibility and the ability to lead a normal life.

42. Dr. Durrani told Plaintiff that his pain and loss of flexibility were completely normal.

43. Plaintiff continued to follow up with Dr. Durrani and CAST until June 2013.

44. Mr. Atwood is now in excruciating pain every day.

45. Mr. Atwood now treats with pain management doctors, spine surgeons, his primary care physician, psychologists, and urologists to try to manage his pain.

46. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

47. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff have surgery.

48. As a direct and proximate result of Mr. Atwood's surgery, Dr. Durrani's negligence, and the Defendants negligence, Mr. Atwood has suffered harm.

49. Plaintiff did not become aware of Infuse/BMP-2 and/or Puregen until he contacted his undersigned counsel.

50. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiff's bills.

REBEKAH BRADY

51. At all times relevant, Plaintiff was a resident of and domiciled in the commonwealth of Kentucky.

52. In January of 2010, Plaintiff experienced low back pain, left leg numbness and swelling, left arm numbness, and headaches; due to Plaintiff's pain, Plaintiff visited her primary care physician who referred her to Dr. Durrani at CAST in Blue Ash.

53. At her initial consultation with Dr. Durrani, Dr. Durrani recommended Plaintiff undergo a lumbar spinal fusion.

54. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

55. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

56. On August 27, 2010, Dr. Durrani operated on Plaintiff's lumbar spine at West Chester Hospital.

57. Upon information and belief, during this surgery, Dr. Durrani used Infuse/BMP-2 or PureGen "off label" without Plaintiff's knowledge or consent, causing Plaintiff harm.

58. Infuse-BMP-2 was used off label. Dr. Durrani states he placed an Axial LIF cage, which is not approved with implantation Infuse.

59. Upon information and belief, Dr. Durrani does not hold the credentials to use the ALIF surgical approach.

60. Infuse/BMP-2 was not listed on the surgical consent forms signed by the client.

61. The use of BMP-2 increases a person's chance of cancer by 3.5%

62. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

63. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

64. After this surgery, Plaintiff continued treating with Dr. Durrani at CAST in Blue Ash, Ohio and Erlanger, Kentucky.

65. Further, after her surgery, Plaintiff experiences severe pain in her back and legs, and numbness in her right side and buttocks.

66. At a follow-up visit, Dr. Durrani told Plaintiff she would fully recover within a few months- he was, however, mistaken.

67. Currently, Plaintiff develops sores at her incision and experiences numbness and swelling in her left leg, as well as pain and stiffness in her lower and upper back.

68. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

69. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff.

Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

70. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

71. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

JENNIFER HICKEY

72. At all times relevant, Plaintiff was a resident and domiciled in the Commonwealth of Kentucky.

73. Plaintiff began treatment with Dr. Durrani on or about February of 2010 for intermittent back pain that she had been experiencing for two years.

74. Dr. Durrani diagnosed Plaintiff with "degenerative thoracic spine" and recommended immediate surgery.

75. In Dr. Durrani OR dictation he stated that from the first surgery on April 19, 2010, that Plaintiff's pre-op diagnosis was "Degenerative spinal stenosis T4-5, 5-6;" however, all radiology, up to that point, clearly indicated no stenosis at any level.

76. On or about April 19, 2010 Dr. Durrani performed surgery on Plaintiff at West Chester Hospital.

77. Immediately following surgery, Plaintiff's back pain increased as well as a new severe nerve pain throughout the thoracic region.

78. Plaintiff informed Dr. Durrani of the increase in pain and Dr. Durrani explained the screws inserted in her back were aggravating the nerve causing pain. Dr. Durrani recommended another immediate surgery.

79. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts, and the suspension was in effect at least through October 5, 2010.

80. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

81. On October 1, 2010, Dr. Durrani performed another surgery on Plaintiff at West Chester Hospital to remove the screws from the first surgery.

82. In the October 1, 2010 procedure, Dr. Durrani lists he performed a "Removal of hardware on the right side from T5-T7, exploration of fusion, T5-6 nerve root compression;" however, there is not any documentation from Dr. Durrani nor a consent signed for any hardware that would have been placed at T7, during her initial surgery on 04/19/10, so it is unclear why and how Dr. Durrani could have removed hardware from the thoracic spine.

83. Immediately following the second surgery, Plaintiff continued to have severe back pain and the continued nerve pain from the first surgery.

84. Plaintiff's pain has increased and continued to the point of being unbearable and affecting all aspects of her daily living.

85. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" without Plaintiff's knowledge or consent, in one or more surgeries causing harm.

86. The use of BMP-2 increases a person's chance of cancer by 3.5%

87. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

88. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

89. Upon information and belief, the surgeries upon Ms. Hickey by Dr. Durrani were medically unnecessary.

90. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

91. As a result of the negligence of the Defendants named herein, Plaintiff has suffered damages including medical expenses, pain, and suffering and loss of enjoyment of life.

92. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

ROBERT & MELANIE HOUGHTON

93. At all times relevant, Robert and Melanie Houghton were residents of and domiciled in the commonwealth of Kentucky.

94. In July 2010, Plaintiff was referred to Dr. Durrani by a family member because of lower back pain.

95. Around this time, Plaintiff experienced lower back pain and occasional tingling in his legs.

96. At his initial visit with Dr. Durrani, Dr. Durrani immediately suggested Plaintiff undergo surgery. Dr. Durrani stated Plaintiff had fractured his back and his vertebrae were compressed.

97. Dr. Durrani assured Plaintiff he could remove all pain and he would be back to work within a few weeks.

98. On July 19, 2010, Dr. Durrani performed a posterior spinal fusion at West Chester Hospital. This surgery was an axial lumbar interbody fusion, posterior spinal fusion, and bilateral formanial decompression.

99. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" without Plaintiff's knowledge or consent, in one or more surgeries causing harm.

100. The use of BMP-2 increases a person's chance of cancer by 3.5%

101. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

102. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

103. After the surgery, Plaintiff experiences severe pain, which was worse than the pain he experienced before undergoing surgery with Dr. Durrani.

104. Plaintiff followed up with Dr. Durrani, who informed Plaintiff that although "everything was perfect," they should do a "second look surgery."

105. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

106. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

107. On August 23, 2010, Dr. Durrani performed a second surgery on Plaintiff.

108. During this second surgery, Dr. Durrani performed a lumbar laminectomy, a lumbar foraminotomy and a lumbar spinal stenosis.

109. After her second surgery, Plaintiff experience severe pain to his back and stomach and had to call 911 for assistance.

110. Once in the emergency room, medical personnel determined his intestinal wall ruptured due to the first surgery and immediate stomach surgery was necessary.

111. Dr. Ondylick performed the emergency surgery and about 6 inches of Plaintiff's intestines were removed.

112. Plaintiff was hospitalized for 9 days following the surgery to repair the damage from Dr. Durrani's first surgery on Plaintiff.

113. Plaintiff has not seen Dr. Durrani since October 16, 2011 and now treats with Dr. John Merling.

114. Currently, plaintiff experiences sever back pain and numbness in his right leg. His right leg also drags and any bending causes his back to collapse. The pain has gotten progressively severe since he began treating with Dr. Durrani.

115. Upon information and belief, the surgeries upon Ms. Hickey by Dr. Durrani were medically unnecessary.

116. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

117. As a result of the negligence of the Defendants named herein, Ms. Hickey has suffered

damages including medical expenses, pain and suffering, and loss of enjoyment of life.

118. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

PAUL MARKSBERRY, JR.

119. At all times relevant, Paul Marksberry J.R., was a resident and domiciled in the Commonwealth of Kentucky.

120. Plaintiff was injured in a motor vehicle accident and was having problems with his left neck and left arm when he was referred to Dr. Durrani and CAST.

121. During his consultation with Dr. Durrani at CAST, Plaintiff informed Dr. Durrani that he wished to have a discectomy of C4 performed pursuant to an MRI report.

122. Dr. Durrani agreed to do it and scheduled him for that surgery; approximately 10 days later, Dr. Durrani changed the procedure to an anterior cervical discectomy C6-C7 with fusion, posterior laminectomy, foraminotomy C5-C6.

123. Throughout Plaintiff's treatment with Dr. Durrani- he recommended other surgeries.

124. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

125. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

126. On October 4, 2010, Dr. Durrani performed the anterior cervical discectomy C6-C7 with fusion, posterior laminectomy, foraminotomy C5-C6 and a L5-S1 AxiLIF on the Plaintiff.

127. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or PureGen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

128. The use of BMP-2 increases a person's chance of cancer by 3.5%

129. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

130. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

131. Following surgery, Plaintiff began experiencing constant burning and an increase in pain, bilateral arms decreased in strength, and Plaintiff also developed a severe infection. Plaintiff did not experience these effect before surgery with Dr. Durrani.

132. Following the October 2010 surgery, Plaintiff continued follow-up with Dr. Durrani at CAST.

133. Plaintiff had to go to his primary care physician for treatment for the infection that he got from surgery with Dr. Durrani.

134. Plaintiff tried to tell Dr. Durrani about how the magnitude of his pain, but Dr. Durrani kept stating in his record how well Plaintiff was doing.

135. When Plaintiff's problems continued, he became upset with Dr. Durrani and sought help from another doctor.

136. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

137. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and

acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failure to disclose vital information, and improperly induced the Plaintiff to have surgery.

138. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.

139. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiff's bills.

HIRAM AND DAWN MCCAULEY

140. At all times relevant, Plaintiffs, Hiram & Dawn McCauley, were married and residents and domiciled in the commonwealth of Kentucky.

141. Plaintiff was told by his primary care physician that he should seek out the services of a surgeon for his back.

142. At the time, Plaintiff was experiencing occasional spasms in his back that were being treated with pain medication.

143. However, due to Plaintiff's employment in a shipping warehouse, constant pain medication was not a tenable solution.

144. Plaintiff's insurance company, Aetna, maintained a list of covered physicians from which Plaintiff selected Dr. Durrani.

145. Dr. Durrani recommended surgery during his consultation with Plaintiff after reviewing Plaintiff's MRI films.

146. Plaintiff was apprehensive of back surgery due to a family history of poor results, and questioned Dr. Durrani on whether the surgery was necessary.

147. Dr. Durrani told the Plaintiff that if surgery was not done on his back that his pain would soon be "far worse."

148. When Plaintiff asked Dr. Durrani what made the proposed surgery likely to succeed, Dr. Durrani informed him that the proposed procedure was a "new surgery" and that Plaintiff would "be better than new when you get done with it."

149. Dr. Durrani further assured Plaintiff that he would be able to return to work within a month following the surgery.

150. Plaintiff informed Dr. Durrani that he did not want to be heavily medicated, and requested that Dr. Durrani limit his use of pain medications.

151. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

152. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

153. On October 4, 2010, Dr. Durrani performed surgery on Plaintiff consisting of a posterior spinal fusion with the installation of hardware from L3-S1 at West Chester Hospital.

154. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

155. The use of BMP-2 increases a person's chance of cancer by 3.5%

156. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

157. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

158. Plaintiff did not see Dr. Durrani after the surgery, and was sent home with no documentation detailing follow-up care.

159. On October 9, 2010 Plaintiff went to the emergency room of St. Elizabeth South to treat severe spasms in his back. Plaintiff was given two injections into his hip and sent home.

160. Within 24 hours, Plaintiff was rushed back to the hospital in extreme and excruciating pain. He was kept in the hospital for a week, and has little memory of this time due to the sheer amount of pain he was suffering.

161. During this week, Plaintiff was treated for severe dehydration and an infection of his surgical incisions.

162. During follow-up visits with Dr. Durrani, Plaintiff informed Dr. Durrani that he was suffering from numbness in his feet as well as pain that radiated down into his legs. Dr. Durrani told the Plaintiff that this was a result of withdrawal from pain medication.

163. Six months later Plaintiff was still experiencing numbness and pain; during his follow-up visit with Dr. Durrani this same pain which had earlier been attributed to overuse of pain medication was now blamed on Plaintiff's diabetes.

164. At Plaintiff's final follow-up with Dr. Durrani, Dr. Durrani attributed Plaintiff's continuing pain to an error with Plaintiff's physical therapy provider.

165. Since Dr. Durrani's surgery, Plaintiff's pain and suffering have increased to the point where he is largely immobile and unable to engage in everyday activities.

166. Plaintiff's left leg is occasionally non-responsive and must be dragged along as Plaintiff walks. Both of Plaintiff's legs with occasionally give out, causing falls and extreme balance issues which Plaintiff has attempted to correct by using a cane.

167. Since the surgery Plaintiff is no longer in control of his bowels, and has likewise lost the ability to engage in marital relations. His back continuously spasms and he is no longer able to work.

168. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

169. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failure to disclose vital information, and improperly induced the Plaintiff to have surgery.

170. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

CAROL ROSS

171. At all times relevant, Plaintiff, Carol Ross, ("Plaintiff" or "Ms. Ross") was a resident of and domiciled in the State of Indiana.

172. In or around late 2008, after experiencing problems with her neck and associated pain, Plaintiff had surgery performed by Dr. Colosimo and Dr. Goldbert at the Good Samaritan Hospital.

173. During the surgery, hardware was inserted into Plaintiff's back.

174. Three months following this surgery, Plaintiff's hardware failed, and Plaintiff was

informed that a second surgery was necessary to correct the problem.

175. Plaintiff scheduled a second, revisionary surgery, with Dr. Chinduri to repair the hardware.

176. On the way to this second surgery, Plaintiff received a phone call from Dr. Durrani requesting that she not go forward with the second surgery and that Plaintiff had become his patient instead.

177. Plaintiff proceeded with the second surgery that day, performed by Dr. Chinduri.

178. The second surgery did not resolve Ms. Ross's pain.

179. Following these surgeries, Ms. Ross was diagnosed with radiculpathy in her right arm, which caused her to lose strength and to be in constant pain.

180. In or around early 2010, Ms. Ross referred herself to Dr. Durrani at CAST.

181. During Ms. Ross's first visit with Dr. Durrani at CAST, Dr. Durrani told Plaintiff that a third surgery was necessary to revise the hardware inserted in her back during the first surgery and to correct her cervical spinal stenosis.

182. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

183. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

184. On or about August 25, 2010, at West Chester Hospital Dr. Durrani performed a C4-S1 posterior spinal fusion, a right sided laminectomy, right sided foraminotomy C4-S1, and a fusion with instrumentation C4-S1 and replaced the hardware previously inserted in Ms. Ross's back.

185. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off –label" and/or Puregen without Ms. Ross's knowledge or consent, causing Ms. Ross harm.

186. The use of BMP-2 increases a person's chance of cancer by 3.5%

187. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

188. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased

189. Ms. Ross continued to experience pain in her right arm and aback after the surgery.

190. On or about September 11, 2012, Dr. Durrani told Plaintiff that a C7-T1 fusion was necessary to correct her cervical stenosis.

191. Dr. Durrani further told Ms. Ross that if she did not undergo this surgery, she would become paralyzed.

192. Plaintiff consulted with Dr. Tayeb, Dr. Nichols, and Dr. Conrad, all of whom advised Ms. Ross that a fourth surgery was not necessary and that she should not proceed.

193. Plaintiff informed Dr. Durrani of the other doctor's concerns.

194. Dr. Durrani convinced Plaintiff that the other doctors were mistaken, and that if she did not have the fourth surgery she would become paralyzed.

195. Dr. Durrani further told Plaintiff that this fourth surgery would "fix her".

196. On or about December 7, 2012, Dr. Durrani performed a C7-T1 anterior cervical discectomy and an anterior cervical fusion with instrumentation on Plaintiff at West Chester Hospital.

197. Dr. Durrani told Plaintiff, prior to the surgery, he would remove a loose screw located in her spine at T1-T2; however, x-ray and cervical CT scan on April 3, 2013 confirmed that the screw is still present at T1-T2.

198. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off –label" and/or PureGen without Ms. Ross's knowledge or consent, causing Ms. Ross harm.

199. The use of BMP-2 increases a person's chance of cancer by 3.5%

200. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

201. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

202. Since the December 7, 2012 surgery, Plaintiff has had extreme pain, she has difficulty moving both arms, she requires increased pain medications, and has extreme difficulty swallowing and breathing difficulties as well.

203. On April 9, 2013, Dr. Durrani's CAST notes state, "This is an issue at this point for which there is no surgical remedy here. I discussed with her that she has chronic neuropathy from all the scarring."

204. Following this surgery, Plaintiff experienced extreme pain in her back.

205. Since Ms. Ross's fourth surgery in or around December 2012, Ms. Ross has been unable to work or live her life as she had prior to undergoing surgery with Dr. Durrani.

206. Ms. Ross further experiences daily increased pain, paralysis, and decreased mobility.

207. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.

208. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

209. As a direct and proximate result of Plaintiff's surgeries, Dr. Durrani's negligence, and the Defendant's negligence, Plaintiff has suffered harm.

210. Ms. Ross did not become aware of Infuse/BMP-2 and/or PureGen until she contacted her undersigned counsel.

MIKE & DIANE SANDER

211. At all times relevant, Plaintiff, Mike and Diane Sander, ("Plaintiff" or "Plaintiffs") were married and were residents of and domiciled in the Commonwealth of Kentucky.

212. In February 2010, Plaintiff began to experience pain in his back after time spent shoveling snow.

213. Plaintiff's primary care physician prescribed painkillers and referred him to Dr. Durrani.

214. In March 2010, Plaintiff had an MRI exam under the direction of Dr. Durrani, the results of which Dr. Durrani interpreted to indicate that Plaintiff had a "bad disc" in his back.

215. Dr. Durrani immediately recommended surgery to correct the problem; no further conservative measures were explored.

216. Dr. Durrani assured Plaintiff that the surgery would "take care of [Plaintiff's] back problem" and that "[he] could go back to a normal life."

217. On July 19, 2010 Dr. Durrani performed surgery on the Plaintiff consisting of: (1) an AxiLIF from L5-S1, (2) a laminectomy from L4-L5 and L5-S1, and (3) a foraminotomy from L4-L5 and L5-S1 at West Chester Hospital ["the first surgery"].

218. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

219. The use of BMP-2 increases a person's chance of cancer by 3.5%

220. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

221. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

222. Plaintiff had follow-up care with Dr. Durrani at his CAST offices after the surgery.

223. After a month of recovery and two weeks of physical therapy along with a pain management course, Plaintiff's pain was worse than ever before.

224. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

225. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

226. On September 22, 2010 Dr. Durrani performed surgery on the Plaintiff consisting of a right side discectomy and laminectomy from L4-L5 at West Chester Hospital ["the second surgery"].

227. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.

228. The use of BMP-2 increases a person's chance of cancer by 3.5%

229. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

230. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

231. Plaintiff continued to have follow-up care with Dr. Durrani at his CAST offices following this second surgery.

232. On December 13, 2010, Dr. Durrani performed a revision surgery on Plaintiff from L4-S1 at West Chester Hospital ["the third surgery"].

233. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this third surgery without Plaintiff's knowledge or consent, causing harm.

234. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

235. The use of BMP-2 increases a person's chance of cancer by 3.5%

236. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

237. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

238. Following this third surgery, Dr. Durrani recommended that Plaintiff engage in a course of physical therapy, but told the Plaintiff that there was "nothing more [he] could do."

239. Prior to having surgical procedures with Dr. Durrani, Plaintiff experienced some lower back pain, as well as pain in his legs with occasional numbness. During this time, Plaintiff was able to continue to work 60 hours per week.

240. Since Dr. Durrani's surgeries, Plaintiff now suffers from extreme pain far worse than anything he had felt prior to July of 2010. He is now on disability, and requires the use of a cane to achieve some small measure of mobility.

241. Plaintiff is unable to sit for long periods of time, and has trouble sleeping due to the pain that he now suffers.

242. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

243. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani's mislead, did not disclose vital information, and improperly induced the Plaintiff do have surgery.

244. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

245. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

DAVID & NANCY SHEMPERT

246. At all times relevant, Plaintiff, David & Nancy Shempert, ("Plaintiff" or "Plaintiffs") were married and were residents of and domiciled in the Commonwealth of Kentucky.

247. Plaintiff sought treatment with Dr. Durrani in May 25, 2010 for lower back pain and pain radiating into his left leg.

248. Dr. Durrani recommended immediate surgery to alleviate the pain. He informed Plaintiff he would be "good as new" and the recovery would be quick.

249. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

250. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

251. On or about September 10, 2010, Dr. Durrani performed a spinal fusion with instrumentation surgery on Plaintiff at West Chester Hospital.

252. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

253. The use of BMP-2 increases a person's chance of cancer by 3.5%

254. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

255. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

256. Plaintiff continued to follow up with Dr. Durrani and complain of continuous back pain. Although the surgery relieved his leg pain, the back pain was intensified.

257. Dr. Durrani told him this was normal and that the pain was also related to the weather

258. Plaintiff continues to experience intense back pain and has lost all flexibility. He is unable to bend over at all.

259. After surgery with Dr. Durrani, Plaintiff now uses pain medications to get through every day activities.

260. Plaintiff is no longer able to perform activities that he once loved like hunting and fishing, play with his, difficulty with long car rides, standing, sitting for any length of time.

261. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

262. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failure to disclose vital information, and improperly induced the Plaintiff to have surgery.

263. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

264. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

RICHARD ALLEN STANFIELD

265. At all times relevant, Richard Allen Stanfield, was a resident of and domiciled in the commonwealth of Kentucky.

266. Plaintiff sought treatment with Dr. Durrani in early 2010 for pain in his lower back radiating down to his right leg and foot.

267. At the first office visit, Dr. Durrani recommended immediate recommended surgery on Plaintiff's spine.

268. Dr. Durrani told Plaintiff that he could "fix him and he would be able to return to work within 5 weeks without pain."

269. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

270. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

271. On August 13. 2010, Dr. Durrani performed surgery on Plaintiff at West Chester Medical Center.

272. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

273. The use of BMP-2 increases a person's chance of cancer by 3.5%

274. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

275. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

276. Plaintiff's back felt extremely stiff and sore following surgery. He continued to follow up with Dr. Durrani and complain to him about the pain. Dr. Durrani told him to give it time and let it heal.

277. Plaintiff's pain continued to increase in his lower back.

278. Plaintiff now lives with constant pain and discomfort as a result of the surgery performed by Dr. Durrani. Plaintiff is constantly stiff with no flexibility and is completely unable to work.

279. Since surgery with Dr. Durrani Plaintiff has not been without pain.

280. After surgery with Dr. Durrani, Plaintiff has difficulty with sitting, standing, walking, laying down, and sleeping.

281. Plaintiff has a weight limit of 5-10 pounds, he is unable to do household chores and depends on assistance for the housework.

282. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

283. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

284. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

285. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

ADDITIONAL BACKGROUND INFORMATION:

286. Defendants fraudulently induced Plaintiff and her insurance company to pay for the surgery.

287. According to CFO Mike Jeffers, West Chester Hospital was in the business of making as much money as possible regardless of their non-profit status.

288. According to CFO Mike Jeffers, it would be against West Chester Hospital's interest to do something that would limit their earning potential or stop making money.

289. According to CFO Mike Jeffers, Dr. Durrani was the highest monthly revenue generator at West Chester Hospital.

290. The Board of Directors of UC Health, according to CFO Mike Jeffers, were aware of the financial growth of the hospital and of the orthopaedic and spine department and in particular the significant financial revenue generated from Dr. Durrani's surgeries.

291. According to CFO, Mike Jeffers, West Chester Hospital billed more for BMP-2 and PureGen then what they purchased the items for.

292. According to CFO, Mike Jeffers, West Chester Hospital tracked the occupancy of their 162 beds by floor.

293. According to CFO, Mike Jeffers, at the end of each month there was a reporting packet that was requested from all the finance directors, and it would be sent to the corporate controller Charity Fannin regarding the monthly finances.

294. According to CFO, Mike Jeffers, the information was tracked by each individual patient in the hospital.

295. According to Annual Reports put together by Jeff Hinds and financial statements of West Chester/UC Health from 2009 through 2013, the Defendants violated R.C. 1702(54), by knowingly placing false information in numerous documents governed by R.C. 1702(54) including over $4 million dollars falsely claimed as income for Medicaid/Medicare fraud and

other false statements in their prospective, reports, financial statements, minutes, records and accounts.

296. West Chester/UC Health made more money from surgical patients than medical patients. Dr. Durrani was a spine surgeon.

297. West Chester/UC Health made more money from more surgical procedures and more diagnostic tests and therapeutic procedures of any kind. Dr. Durrani ordered significant unnecessary diagnostic tests and procedures for his patients and the Defendants knew this fact.

298. Complex cases made West Chester/UC Health more money than simple ones. Dr. Durrani had complex cases.

299. There have been serious consequences since orthopedic device companies began sending sales representatives to the operating room of hospitals as they did and do to West Chester/UC Health.

300. The sales representatives assist the back table with the instruments, technique and managed inventory. This has allowed the hospitals to allow their staff to not know specifics about cases and orthopedic systems. This has also allowed the hospitals to avoid the cost of training their staffs for what the sales representatives do. This all applies to West Chester/UC Health

301. The sales representative adds approximately 40% to the cost of the implant and increases implant usage to 30% at West Chester/UC Health.

302. The Dr. Durrani saga at West Chester is Exhibit A of the medical complex run amok for profit and greed over patient care.

303. West Chester/UC Health failed to report a single incident of any kind involving Dr. Durrani to the National Practitioner Data Bank and any other reporting agency including the Ohio Medical Board despite there being countless required reports.

304. According to HRSA Data, 42% of hospitals have never made a single report to NPDB.

305. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

306. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

307. From January 2009 through May 2013, with respect to Dr. Durrani, Defendants failed to follow their Medical Staff Code of Conduct which they approved as witnessed by Ed Crane, President of the Medical Staff and Paula Hawk.

308. Unknown Defendants include all Members of the Executive Committee, Credentialing Committee and Peer Review from 2009 through 2013.

309. Article I of the MEC bylaws gives the MEC "oversight," of quality of care and patient safety for West Chester.

310. Article 3.1.1 sets forth who the officers are including President, Director of Surgery, Director of Medicine and Chair of Credentials Committee.

311. Article 3.3.1 provides the duties of each department director and Article 4.4 provides the functions of the department.

312. Defendants have refused to produce through discovery the members of West Chester's Medical Executive Committee, Credentialing Committee and Peer Review Committee from 2009 through 2013.

313. According to Barbara Butz, she prepared the application for credentials to be reviewed by the department directors, the credentialing committee, the MEC and the Board.

314. According to Grant Wenzel, there was a marketing campaign that "spoke of our capabilities" in spine surgery.

315. West Chester/UC Health and the Defendants allowed Dr. Durrani from at least August 1, 2010 to October 5, 2010 to perform surgeries at West Chester while suspended. Over 30 patients had surgeries during this time period. This intentional egregious conduct is appalling and represents fraud in the concealment. None of these 30 plus patients would have allowed Dr. Durrani to perform their surgery had they known Dr. Durrani was suspended.

316. West Chester/UC Health and Defendants bragged about and still brag about their spine surgery capabilities.

317. West Chester/UC Health failed to comply with their Medical Staff Bylaws which include:

a) Bylaws

b) Credentialing Plan

c) Rules and Regulations

318. The list of negligent acts, intentional acts and fraudulent acts by Dr. Durrani known to the hospital management, administration and board members including these Defendants include:

1) Dr. Durrani was the #1 money making doctor for West Chester.

2) West Chester planned to lease Dr. Durrani the fourth floor of the hospital for CAST physical therapy.

3) According to Paula Hawk, West Chester and Dr. Durrani were "partners in crime."

4) West Chester allowed three days of blocked surgery time and allowed more than one surgery at a time.

5) West Chester ignored their Medical Executive Committee bylaws when it came to credentialing and retaining Dr. Durrani.

6) West Chester West Chester/UC Health knew BMP-2 was being used improperly by Dr. Durrani including in minors, non-approved locations in the spine and in patients with cancer risks.

7) West Chester/UC Health knew Dr. Durrani was doing extensive multiple surgeries on patients.

8) West Chester/UC Health knew of Dr. Durrani's issues at other issues at hospitals before his application of privileges at West Chester.

9) West Chester/UC Health knew about the "Shanti Shuffle" which is an expression to describe Dr. Shanti, Dr. Durrani's employee spine surgeon, performing spine surgeries for Dr. Durrani without the consent of the patient.

10) West Chester/UC Health knew about "emergency" add on issue where Dr. Durrani would claim a surgery was an emergency to add it on to an existing schedule.

11) West Chester/UC Health knew PureGen was being used improperly by Dr. Durrani including that was never approved for human use and they bought it from Dr. Durrani.

12) West Chester/UC Health knew Dr. Durrani was the biggest revenue generator.

13) West Chester/UC Health knew Dr. Durrani would perform multiple surgeries at the same time in the OR.

14) West Chester/UC Health knew Dr. Durrani was not dictating OR reports or dictating them extremely late, often times up to six months.

15) West Chester/UC Health knew Dr. Durrani's patients had extended anesthesia waiting for surgery.

16) West Chester/UC Health marketed themselves as a world leader in spine surgery.

17) West Chester/UC Health knew Dr. Durrani was "over-utilizing."

18) The officers and administrators in depositions have admitted West Chester/UC Health knew of the issues involving Dr. Durrani.

19) West Chester/UC Health knew Dr. Durrani was not obtaining proper informed consents from his patients.

20) West Chester/UC Health knew Dr. Durrani dictated discharge summaries late and sometimes not at all.

21) West Chester/UC Health knew they were not following their bylaws, rules and policies in their supervision of Dr. Durrani.

22) West Chester/UC Health knew Dr. Durrani was abusive to staff.

23) West Chester/UC Health knew Dr. Durrani was "sloppy" in surgery.

24) West Chester/UC Health knew staff and medical staff would lie regarding Dr. Durrani issues.

25) West Chester/UC Health forced silence upon staff and medical staff.

26) West Chester/UC Health tracked BMP-2 use by Dr. Durrani to calculate their profits from its use.

27) West Chester/UC Health knew Dr. Durrani performed surgeries too late into night to the detriment of patient safety.

28) West Chester/UC Health knew Dr. Durrani's use of improper hardware in spinal surgeries.

29) West Chester/UC Health knew Dr. Durrani sometimes marketed himself as a neurosurgeon to patients.

30) West Chester/UC Health knew Dr. Durrani performed procedures beyond his scope of practice and training.

31) West Chester/UC Health knew Dr. Durrani performed surgeries with inadequate training.

32) West Chester/UC Health knew Dr. Durrani used "cut and paste" in his OR reports.

33) West Chester/UC Health knew Dr. Durrani engaged in improper financial relationships with orthopaedic product vendors.

34) West Chester/UC Health knew Dr. Durrani had the lack of attention to detail as required of a spinal surgeon.

35) West Chester/UC Health knew multiple Dr. Durrani patients suffered from improper VATS procedures, resulting in various reactive airway diseases postoperatively.

36) West Chester/UC Health knew they did not do proper credentialing procedures of Dr. Durrani prior to privileging him as a surgeon.

37) West Chester/UC Health knew Elizabeth Garrett (physician's assistant) was present and active in the OR as an assistant surgeon without the proper approval.

38) West Chester/UC Health allowed and promoted Dr. Durrani to give seminars knowing he misrepresented his status at Children's Hospital and University Hospital.

39) West Chester/UC Health knew Dr. Durrani had an improper personal relationship with Elizabeth Garrett.

40) West Chester/UC Health knew that the required tracking paperwork of BMP-2 and PureGen was not routinely completed in the OR.

41) West Chester/UC Health knew Dr. Durrani's patients were having anesthesia related complications intraoperatively and postoperatively, and did not disclose it to patients.

42) West Chester/UC Health knew Dr. Durrani failed to disclose to patients and family medical problems encountered during surgery.

43) West Chester/UC Health knew Dr. Durrani was creating health care billing fraud and they too committed billing fraud.

44) West Chester/UC Health knew Dr. Durrani handpicked patients with optimal health insurance for unnecessary surgeries to profit himself and the hospital.

45) West Chester/UC Health knew Dr. Durrani often did not contact his patient's primary care practitioner for in-patient hospital follow up appointments, and instead picked West Chester staff to cover maximize profit, and not have to disclose his wrongdoings.

319. The hospital's management administration and board members, including the Defendants, knew of the improper use of BMP-2 and PureGen by not only Dr. Durrani, but other surgeons. This Complaint contains detailed sections pertaining to these two substances.

320. There were over 185 BMP-2 victims and over 84 PureGen victims at West Chester/UC Health, all Dr. Durrani patients. There are hundreds and even probably over a thousand or more past patients of West Chester/UC Health who have no idea they have BMP-2 or PureGen in their spines and they are encountering health issues they have no idea could be caused by BMP-2 or PureGen. Two separate class actions on this issue will be filed simultaneous with this lawsuit.

321. The Annual Reports of UC Health reflect the bragging by the management, administration and board, including Defendants, of West Chester's financial performance and spine awards with full knowledge of the false information contained in them including over $4 million in fraudulent Medicaid and Medicare billings. The one for the Fiscal year ended June 30, 2013 is the last one applicable to Dr. Durrani, his last year at West Chester.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

323. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

324. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

325. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

326. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

327. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

328. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

329. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

330. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

331. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

332. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

333. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

334. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

335. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

336. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

337. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

338. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

339. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

340. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

341. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

342. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

343. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

344. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

345. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

346. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

347. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

348. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

349. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

350. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

351. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

352. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

353. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

354. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

355. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

356. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

357. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

358. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

359. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

360. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

361. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

362. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

363. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

364. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

365. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

366. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

367. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

368. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

369. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

370. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

371. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

372. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

a. Recombinant – Artificially created in a lab;

b. Morphogenetic – Evolutionary development of an organism;

c. Protein – Essential for growth and repair of tissue.

373. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

374. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

375. BMP-2 has been shown to stimulate the production of bone.

376. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

377. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

378. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service ActSec.351(i)1."Available http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

379. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

380. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

381. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

382. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

383. The second part of the bone graft is an absorbable collagen sponge.

384. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

385. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

386. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

387. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

388. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

389. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

390. Infuse should never be used in the vicinity of a resected or extant tumor.

391. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

392. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

393. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[1]

394. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[2]

395. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

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[1] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[2] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

396. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

397. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[3]

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[4]

See Medtronic Package Insert, "INDICATIONS."

398. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

E. Bone fracture

F. Bowel/bladder problems

[3] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

[4] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

O. Dural tears

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

399. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

400. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

401. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

402. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

403. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

404. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

405. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA ... [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

406. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

407. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

408. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

409. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

410. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

411. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

412. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

413. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

414. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

415. Medtronic anticipated that both products would initially be limited in application.

416. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

417. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA.

However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

418. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

419. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

420. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

421. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine,* which followed industry standards before printing peer-reviewed material. See article in the journal *Spine,* published in 2000.

422. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of

medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

423. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

424. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

425. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

426. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if

the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

427. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

428. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen-year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

429. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

430. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

431. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

432. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one-year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

433. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

434. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

435. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

436. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each

and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

437. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

438. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

439. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

440. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

441. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"

442. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

443. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

444. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

445. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "…may become the new gold standard in spinal fusion surgery."

446. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

447. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

448. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

449. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

450. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

451. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

452. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

453. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

454. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

455. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

456. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

457. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury.

458. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

459. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

460. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

461. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

462. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

463. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

464. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

465. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

466. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

467. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

468. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and

benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

469. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

470. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

471. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine,* the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

472. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

473. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

474. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

475. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

476. In total, the YODA study analyzed the data from 1,409 participants.

477. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

478. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

479. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

480. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

481. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

482. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

483. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

484. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

485. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

486. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

487. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

488. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

489. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

490. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

491. BMP-2 is not supposed to be used in minors.

492. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

493. BMP-2 should not be used with women in child bearing years.

494. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

495. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

496. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

497. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

498. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

499. Dr. Durrani was a paid consultant for Medtronic.

500. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

501. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

502. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

503. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

504. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

505. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

506. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

507. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

508. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

509. Medtronic's website has no information regarding their relationship with Dr. Durrani.

510. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

511. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

512. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

513. Again, this information is not available on the Medtronic website.

514. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

515. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

516. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

517. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

518. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

519. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute,

which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

520. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

521. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

522. David Rattigan, was Dr. Durrani's main Medtronic representative from Bahler Medical.

523. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition was taken June 5, 2015.

524. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

525. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

526. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

527. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

528. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

529. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

530. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

531. **Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

532. The Defendants had the responsibility to carry out these consent rules.

533. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

534. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

535. Dr. Durrani is a consultant for Medtronic.

536. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

537. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

538. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

539. BMP-2 is neither safe nor approved for use on children less than twenty-one (21) years of age.

540. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

541. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

542. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

543. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

544. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

545. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

546. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

547. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

548. Plaintiffs would not have consented to the use of BMP-2 in Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

549. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

550. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

551. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

552. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

553. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

554. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

555. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

TRIGGERS - RETENTION

556. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

557. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

558. The following are the triggers for peer review or other actions as provided by West Chester/UC Health to the Deters Law Office in discovery in related litigation and is a list which by their own admission is not exclusive and is a list they produced after full knowledge of the items Dr. Keith Wilkey, Plaintiffs' experts, considered triggers:

A. Wrong operative procedure performed

B. Serious injury due to medical device

C. Procedure performed on wrong patient

D. Medication resulting in death

E. Delay in diagnosis

F. Autopsy not correlated with clinical diagnosis

G. Delay in treatment resulting in serious injury or death

H. Alleged abuse or neglect

I. Unexpected death

J. Surgical death

K. Mortality review

L. Unplanned second surgeon called to OR

M. MD not credentialed for procedure

N. Focus review

O. Incident reports

P. Contraindication to surgery

Q. Unintended retention of foreign object in a patient after surgery

R. Complications from procedure (i.e. readmits, infections, pneumothorax after procedure)

S. X-ray discrepancies

T. Returns to surgery

U. Transfusion not meeting criteria on order sheet

V. Change in surgery/procedure

W. Laceration/or perforation/puncture of organ during invasive procedure

X. Acute MI or CVA within 48 hours of procedure

Y. Anesthesia complications

Z. MD without timely response to ED or unit call

AA. Risk management issues

BB. Delay in treatment not resulting in serious injury and/or death

CC. Delay in diagnosis not resulting in injury or death

DD. Acute blood loss as indicated by procedure

EE. Appropriate care measures not ordered

FF. Readmission- complication of previous admission

GG. Unplanned admission following surgery

HH. 72 hours returns to ED and readmit same issue

II. Insufficient documentation

JJ. BMP-2

KK. PureGen

LL. Late dictation or no dictation of operative reports or discharge summaries

MM. False claim of spondylolisthesis

NN. False claim of stenosis or its severity

OO. Performing surgeries on patients whose health condition vitiates surgery: age, diabetes, obesity, hypertension, mental health issues, etc.

PP. Shanti Shuffle- Dr. Shanti being forced to do an entire surgery for Dr. Durrani by Dr. Durrani without the patient's knowledge.

QQ. No hospital consents or improper CAST consents

RR. Failed Hardware

SS. Performing surgery not qualified to perform

TT. Dura tear

UU. Having hardware which should be removed, which is never removed

VV. Not using the proper cage with BMP-2

WW. Ignoring radiology results

XX. Misrepresentations to primary care physicians

559. Dr. Keith Wilkey, a board certified spine expert, has reviewed over 213 patient charts at West Chester of Dr. Durrani and signed 213 affidavits of merit as required under CR10 of Ohio Rules of Procedure to file a medical malpractice case and based upon these reviews over 500

events triggers place which would have required action against Dr. Durrani by West Chester. Defendants intentionally took no action.

560. In 2008, insurance companies became much more selective in what they would authorize for payment. They started only paying for spinal surgeries that were highly indicated, meaning there was rock solid medical evidence to support their necessity for treatment of patients.

561. Certain diagnoses such as spondylolisthesis and severe spinal stenosis have good literature support for complicated lumbar fusion procedures with instrumentation, highly indicated procedures with good outcomes which result in; more pay for Durrani. Dr. Durrani would use these extensively. The data shows Dr. Durrani falsely claimed spondylolisthesis diagnosis 95% of the time.

562. Most of the surgeries Dr. Durrani actually performed were a lesser indication; mainly degenerative disc disease with lesser amounts of spinal stenosis which insurance companies will not usually pay for the more expensive spinal fusion; less pay for Dr. Durrani. This is why Dr. Durrani would claim the conditions of spondylolisthesis.

563. Surgeons have to obtain advanced authorizations from the patient's insurance carrier prior to doing the surgery. If surgeons are requesting to do a surgery with a lesser indication, most of the time it is denied unless the requesting surgeon can convince a "peer surgeon" of the need to do the bigger surgery and demonstrate why this case is an exception to their policies. That takes time and the peer has access to the patient's whole medical record. That peer reviewer could easily have discovered the fraudulent diagnoses Durrani was claiming.

564. Beginning in 2009, Dr. Durrani lied much more often to avoid the whole process and possibility of discovery by the insurance companies.

565. Dr. Durrani didn't do his operative reports on time so as to assist his cover-up of the fraudulent diagnoses.

566. Government has given hospitals incredible power to act as the "watch" for patient's safety and well-being, but with that power comes responsibility.

567. West Chester Hospital had the duty to monitor its physicians via the peer review process and at least on paper, they had the process in place.

568. In that process, West Chester had several "triggers" established which would have resulted in an in-depth peer review. Triggers don't have to be events or behaviors that are malpractice, but are designed to be even more sensitive.

569. Most of those triggers are suggested by the government such as complications and return to surgery. However, hospitals are supposed to adjust their triggers for the individual physicians depending on their practice type and behaviors. This is to insure that the hospital has meaningful triggers for each physician. It wouldn't make sense to monitor operative reports for an internist that doesn't operate. It would make more sense to look at his discharge summaries.

570. For Dr. Durrani, meaningful triggers would have been items tracked during the medical record review of the malpractice claims. Although complications such as hardware failure, nonunion and revision are not mandated by the government for hospital triggers, any responsibility peer review committee should have reviewed Dr. Durrani's results and adjusted the triggers for Dr. Durrani to reflect his higher than normal complication rate in these areas. Other areas tracked should have included his off-label and contraindicated use of Infuse and PureGen.

571. Defendants failed to act upon an overwhelming amount of material. There were over 591 individual triggers that were ignored by West Chester. That is overwhelming and unforgivable for a hospital to allow, given the power they had to protect their patients from harm.

572. On peer review, they are asked to identify and assist with the removal of known incompetence. A surgeon's duty on the peer review panel is to protect patients from illegal operations. Surgeons look for false and fraudulent diagnoses plus fictitious medical treatment.

573. The peer review committee is asked to sit on the committee for usually two years at a request.

574. West Chester Hospital had bylaws based upon the joint commission accreditation of healthcare organizations known as "The Joint Commission." The principles of the initial credentialing that allowed Dr. Durrani to start operating and mechanisms available to the hospital to stop him from harming other patients a basically equivalent. There are some "minor" variations between state laws but for the most part, they are the same. An example would be the "process" called summary suspension, after it becomes clear of a physician's incompetence, the mechanism to remove him are the same everywhere. Therefore, the situation regarding West Chester and Dr. Durrani are unique only in their depth and degree to which Dr. Durrani's egregious behavior was allowed to harm patients before he was stopped only by the filing of over one hundred lawsuits.

575. The credentialing and peer review work is kept secret from the public.

576. Credentialing is a very lengthy application where 40 to 100 pages of documents are required. Each of these have to be verified by the credentialing personnel from the hospital and then a committee member is assigned to do a further background check into these applicants past work to include calling references, hospitals and training programs.

577. Within some broad limits, one can probe very deep into the past of an applicant because the applicant signs multiple disclosure agreements before the background check. This insures that if needed, the peer review can make good recommendations to the committee chairperson.

578. Given Dr. Durrani's behavior and clinical problems in Cincinnati at the time he was applying for credentials at West Chester, phone calls should have been made regarding Dr. Durrani's past work history, particularly at Children's Hospital. Another "red flag" that Dr. Durrani would have had was the fact he was not board certified by the American Academy of Orthopedic Surgeons or a member of the North American Spine Society.

579. Being board certified and a member of a specialty society is a good way for a hospital to have some external quality check for the applicant. If the applicant doesn't have those in their packet, it's a "red flag" and the reviewer for the committee has to be vigilant and do extra digging.

580. If West Chester and Defendants had called and received reports not favorable to Dr. Durrani the information would be confidential and administration could still take a chance and convince the physicians of the credentialing committee and MEC to allow the privileging anyway. Privileging under these circumstances is usually granted by the staff with very strict terms and the physician would be on a very "short leash."

581. If this happens, the physician is put on a strict probationary period with any violation of the bylaws resulting in termination and databank report is filed.

582. Dr. Durrani was incompetent and he should have had an immediate summary suspension and a National Practitioner's Databank report should have been filed after a fair hearing confirmed the initial suspension. This report would be the only way the public would know that Dr. Durrani was found to be incompetent by his peers at West Chester. This report did not

happen and the hospital administration officers, Board members and Defendants were protecting Dr. Durrani from the usual process of peer review.

583. The hospital administration has considerable control of the peer review process. They rightly claim the actual process of reviewing the patient's records and voting on the issue at hand is done by the hospital medical staff. The administration controls all the remaining variables; the physicians assigned to the committee are assigned to review the individual case, which physician is reviewed and the selecting "triggers" for the process and, the "assistants of the committee" that monitor physicians on a daily basis are all hospital employees.

584. According to a review report of Dr. Durrani performed by Dr. Keith Wilkey, 8 of 16 patients OR reports were not done in a thirty-day window, it included a lot of fictitious, fraudulent and false diagnoses, two contraindicated use of Infuse used in minors, one cancer after Infuse and several novel surgeries—VATS, AxiaLIF, DLIF. The results of this peer review speak for itself. Had this study been completed, there is no way to conclude otherwise that Dr. Durrani was incompetent. He should have been summarily suspended before the study was done to protect future patients. The peer review should have reported to the MEC and then Dr. Durrani should have been suspended until a hearing at the MEC level confirmed or denied the summary suspension. A databank report would have been required to be filed by West Chester.

585. West Chester's bylaws clearly state the requirement that OR reports be done within 30 days from the completion of the surgery. Without exceptions, physicians get written notification of their delinquent records and are given anywhere from seven to ten days to correct the deficiency. If the charts are not dictated within that time limit, the physician is summarily suspended and the case is sent to the MEC for their review. This process may be repeated one or two more times, but usually within a six-month period, the delinquent physician has their

privileges revoked and a databank report filed. Dr. Durrani was given an exception for over four years.

586. Defendants willingly overlooked illegal operations. Dr. Durrani gave false or exaggerated and fraudulent diagnoses plus fictitious medical treatment. His surgical outcomes were horrible.

587. The hospital has to disclose the OR reports and the report included the time and the date of the dictation, to which the delay from the surgery date can be determined. West Chester had to disclose emails between the hospitals and Dr. Durrani. In one email from the CEO, Defendant Joseph to Dr. Durrani, the CEO acknowledges that they knew of Dr. Durrani's dictation violations. Therefore, they had actual knowledge of Dr. Durrani's violations and cannot claim a statutory presumption of immunity from negligent credentialing.

588. The Joint Commission sets the standard and hospital compliance isn't controlled by the state. Hospitals have to have ongoing physician monitoring in place to satisfy the accreditation requirements. Good hospitals require a medical staff that is willing and able to monitor itself through Practitioner Performance—ongoing professional practice evaluation "OPPE."

589. Since 2009, the Joint Commission has required hospitals, through its medical staff, to conduct an ongoing professional practice evaluation of every privileged practitioner at the hospital, without exception. There are three essentials to OPPE: it must measure certain things (for surgeons, surgical complications and treatment patterns), the measures must be collected and assessed (periodic chart review, observation, discussion with other doctors and nurses), and finally the medical staff must act on its findings (focused professional performance evaluation instituted.) It is a confidential process.

590. Due to the confidentiality, Dr. Durrani's OPPE from the hospital is not available but because West Chester is joint commission accredited and they supposedly meet all their requirements, it is safe to conclude the OPPE process was done two or three times on Dr. Durrani. Once he started at West Chester and then before his re-credentialing every two years. He either resigned, did not reapply, or was revoked around his four-year re-credentialing.

591. There is another instance where West Chester administration should have known about the other Dr. Durrani issue in that if the OPPE found problems, the MEC should have required a FPPE, which is an in-depth review with the possible requirement for corrective action, summary suspensions, and recommendation of limitation or termination of privileges. If a FPPE was ongoing and Dr. Durrani resigned during this process, a Databank report should have been filed, which didn't happen.

592. Anytime an event occurs that is significant, called a "trigger" OPPE or an FPPE can be conducted, and given Dr. Durrani's poor performance that should have occurred given a medical staff that was diligent in their duties. The administration had multiple warnings from the medical staff about Dr. Durrani. They knew he was bad and ignored that fact.

INFUSE/BMP-2

593. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

594. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

595. Dr. Durrani is a consultant for Medtronic.

596. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

597. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

598. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

599. BMP-2 is neither safe nor approved for use on children less than twenty-one (21) years of age.

600. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

601. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

602. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

603. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

604. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

605. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

606. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgery.

607. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

608. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

609. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

610. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

611. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

612. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

613. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

614. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

615. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

PUREGEN NARRATIVE

PUREGEN BACKGROUND

616. PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

617. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a "biologic" by 42 U.S.C. 351(i) and a "drug" as defined by U.S.C. 321(g).

618. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

619. When used off-label, as Dr. Durrani often did, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord.

620. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

621. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.

622. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.

623. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.

624. Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed Puregen.

625. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

626. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.

627. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.

628. The study population were 50 male/female subjects 18 years and older suffering from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.

629. The clinical trial required:

a. Inclusion

i. Age over 50

ii. Side-by-side use of Puregen and Autologous bone in the same patient for radiographic comparison

iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1

iv. Subjects with back and/or leg paint indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion

v. Unresponsive to conservative treatment for at least 6 months

vi. Radiographic evidence of primary diagnosis

b. Exclusion:

vii. No healthy volunteers permitted

viii. More than two levels requiring posteriolateral fusion (PLF)

ix. Spondyliosis greater than Grade 1

x. Prior failed fusion surgery at lumbar level(s)

xi. Systemic or local infection in the disc or cervical spine, past or present

xii. Active systemic disease

xiii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

xiv. Use of other bone graft, Bone Morphogenic Protein (BMP), or bone graft substitutes in addition to or in place of those products specified

xv. BMI greater than 40

xvi. Use of post-operative spinal cord stimulator

xvii. Known or suspected history of alcohol and/or drug abuse

xviii. Involved in pending litigation or worker's compensation related to the spine

xix. Pregnant or planning to become pregnant during the course of the study

xx. Insulin-dependent diabetes mellitus

xxi. Life expectancy less than duration of study

xxii. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xxiii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xxiv. Known history of hypersensitivity or anaphylactic reaction to dimenthyl sulfoxide (DMSO).

630. All 3 clinical trials were "Terminated" before any results were produced.

631. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

632. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

633. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.

634. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

635. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d).

636. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.

637. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

638. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

639. The FDA stated that PureGen, "does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function."

640. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regards to PureGen. Defendants knew all this.

641. Given this lack of a valid biologics license, the FDA determined that the marketing of PureGen violated both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

642. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, "Both Alphatec Spine and Parcell Laboratories are fully

committed to work closely and collaboratively with the FDA to address the questions related to the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date." See article "Alphatec comments on FDA's letter regarding PureGen product for spinal fusion procedures", Spinal News International, July 28, 2011, attached as Exhibit E.

643. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were "Terminated" and no data was released as to the findings.

644. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

645. Furthermore, according to sales representative, Thomas Blank, Alphatec falsely informed distributors of PureGen that they "resolved" the issues addressed in the FDA letter, did not have to take PureGen off the market and it was "ok" for their distributors to continue marketing and selling PureGen.

646. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.

647. PureGen further stated that it had been placed in these 3,500 patients with "no adverse events related to the product", despite no study, statistics or information to back up such a claim.

648. This 2012 annual report also identified PureGen as a biologic.

649. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as exhibit H.

650. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

651. It is the position of the Deters Law Firm that the distribution and use of PureGen by Dr. Durrani, Evolution Medical, Alphatec Spine, Inc., and West Chester/UC Health by Defendants is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

652. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301". Defendants violated this provision.

653. A "New Drug" is defined as "Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Ohio Revised Code 3715.01(9)(a).

654. PureGen's status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: "A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or

arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)." See http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

655. It is the position of the Deters Law Firm that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A). The Defendants with full knowledge and intent violated this statute.

PUREGEN AT THE HOSPITALS

656. On October 10, 2011, UC Health began purchasing PureGen from Alphatec. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributer of PureGen for the Northern Kentucky/Cincinnati area.

657. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.

658. Thomas Blank worked directly with Alphatec Spine, Inc. and Defendants in the marketing and distribution of PureGen.

659. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc.

660. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority.

661. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.

662. On July 20, 2012, UC Health with the full knowledge and consent of Defendants began purchasing PureGen from Evolution Medical, LLC.

663. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital was handled by UC Health Purchasing.

664. The Defendants tracked West Chester/UC Health's purchases of PureGen from Evolution medical.

665. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani and other doctors who used the product.

666. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.

667. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.

668. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.

669. Defendants would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.

670. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI AND PUREGEN

671. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PureGen is "essentially stem cells" and that he "used to use [PureGen] for a certain amount of time." Deposition of Dr. Durrani in *Brenda Shell v. Durrani*, p. 25-26, attached as Exhibit N.

672. This "certain amount of time" was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

673. Though downplaying his involvement with PureGen, Dr. Durrani, through his illegal POD Evolution Medical, distributed PureGen to West Chester/UC Health with the full knowledge and consent of Defendants.

674. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox and Defendants, knew the Department of Health and Human Services and the United States Senate Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD's).

675. Dr. Durrani and Toby Wilcox's actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.

676. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.

677. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).

678. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani, CAST, Alphatec and the Defendants experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients, and subsequently billing their health insurance companies all while concealing the true nature of their actions.

679. Dr. Durrani also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

680. Dr. Durrani experimentally used Puregen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.

681. Dr. Durrani, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.

682. Dr. Durrani would sell WCH and the other hospitals the PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries.

683. Dr. Durrani and Defendants knew such an arrangement was either unethical and illegal (though still not disclosing the use of PureGen) by having the patients sign an Acknowledgement of Potential Conflict of Interest form.

684. WCH and Defendant also benefited from this arrangement by up charging patients for the PureGen after purchasing it from Evolution Medical and Dr. Durrani.

685. At all times relevant, Dr. Durrani and Defendants was in exclusive control of the amount and ratio of Puregen bone graft that was experimentally implanted into patients.

686. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.

687. Dr. Durrani and Defendants did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.

688. The basic "Informed Consent Forms" Dr. Durrani and CAST did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body.

689. In fact, Dr. Durrani and Defendants would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet "Do Not Bill" twice in regards to PureGen.

690. Implanting Puregen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath's statement "I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone." It is criminal.

PUREGEN AND OUR CLIENTS

691. What follows are just a few examples of the damage caused Dr. Durrani and the Defendants deceptive and fraudulent use of PureGen in Deters Law Office clients without their consent.

692. A majority of these surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.

693. Following the cervical surgeries in which Puregen was implanted, the patients' pain became far worse and more extreme.

694. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.

695. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.

696. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

697. Below are some of the clients experiences since having the Puregen implanted:

698. "I have severe low back pain, stiffness, decreased range of motion and tenderness. Pain radiating to left posterior thigh and right/left lumbar area. Onset months ago after surgery." – William Hayes

699. "Constant, irritating pain, less intense but still present. Even after two surgeries, I continue to have limited use of my left leg. The pain is ever-present. I am easily fatigued and have severe pain after brief tasks such as cooking dinner, preaching a sermon, even making a bed. Bending over is so painful and produces such instability that my family helps put on my socks and shoes. I require a cane for ambulation, due to left leg weakness and limited range of motion." – Darrell Earls

700. "Severe spin in my neck, arm, shoulder blades. Pressure on my throat making it unbearable to swallow meds and food. Loss of range of motion in my neck and stiffness in back. The pain is so severe that I can no longer sleep laying down. I have to sleep sitting up. The pain in my neck is unbearable most days. The pain runs between my shoulder blades into my chest and in my throat and side of my neck." - Duane Pelfrey

701. "I feel I have lost a lot of the flexibility in my neck and back. I have lower back pain, tightness in neck and shoulders, and have a hard time lifting/standing for long periods of time. When I bend over, I have a hard time straightening back up to an upright position." - Dana Conley

702. "Low back pain radiating into bilateral hips, buttocks, legs and feet. Bilateral leg weakness. Numbness in left foot and toes. Bilateral buttock and posterior thigh muscle spasms. Burning sensation in right abdomen that radiates around to back. My post-surgery MRI and CT scan showed bony overgrowth into the foramen and into the canal on left at L5-S1." - Julie Martin

703. "I experience pounding headaches that are far worse than anything prior to surgery. Left leg is numb, painful and swollen, muscle spasms occurring in hip and bilateral legs since surgeries with Dr. Durrani. My whole back, neck and leg hurt so bad I could throw up." - Tonia McQueary

704. "I have much more pain. Constant right-sided headache, intensity varies but always present. The back of my neck swells. My esophagus feels like it is in a different place. My throat swells." – Kelly Hennessey

705. As stated, there are just a few examples of clients that have been discovered to have had non-FDA approved PureGen implanted into their bodies without their informed consent, in violation of both Federal and State Law, all with the knowledge of Defendants.

706. Dr. Durrani oftentimes used Puregen when performing surgeries.

707. Puregen is a product produced by Alphatec Spine.

708. Dr. Durrani was and is a paid consultant for Alphatec Spine.

709. Dr. Durrani has an ownership stake in the Alphatec Spine.

710. Puregen has never been approved by the FDA for any human use.

711. Puregen is now removed from the market for any use.

712. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

713. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

714. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

715. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel that Dr. Durrani used Puregen in her surgeries.

716. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA.

717. Plaintiff would not have consented to the use of Puregen in their body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

718. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in her procedures.

719. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

720. Defendant Dr. Durrani owed his patients, Plaintiffs, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

721. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiffs, including but not limited to improper selection

for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

722. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: BATTERY

723. Dr. Durrani committed battery against Plaintiffs by performing a surgery that was unnecessary, contraindicated for Plaintiffs' medical conditions, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiffs.

724. Plaintiffs would not have agreed to the surgeries if they knew the surgeries were unnecessary, not approved by the FDA, and not indicated.

725. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: LACK OF INFORMED CONSENT

726. The informed consent forms from Dr. Durrani and CAST which they required Plaintiffs to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

727. In addition, no one verbally informed Plaintiffs of the information and risks required for informed consent at the time of or before Plaintiffs' surgery.

728. Dr. Durrani failed to inform Plaintiffs of material risks and dangers inherent or potentially involved with the surgeries and procedures.

729. Had Plaintiffs been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiffs would not have undergone the surgery or procedures.

730. As a direct and proximate result of the lack of informed consent, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

731. Dr. Durrani's conduct as described above was intentional and reckless.

732. It is outrageous and offends against the generally accepted standards of morality.

733. It was the proximate and actual cause of Plaintiffs' psychological injuries, emotional injuries, mental anguish, suffering, and distress.

734. Plaintiffs suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

735. Dr. Durrani made material, false representations to Plaintiffs and their insurance company related to Plaintiffs' treatment including: stating the surgeries were necessary, that Dr. Durrani "could fix" Plaintiffs, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiffs would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiffs were medically stable and ready to be discharged.

736. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiffs' surgery, as well as other information, when he had a duty to disclose to Plaintiffs his planned use of the same.

737. These misrepresentations and/or concealments were material to Plaintiffs because they directly induced Plaintiffs to undergo her surgery.

738. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

739. Dr. Durrani made the misrepresentations before, during and after the surgeries with the intent of misleading Plaintiffs and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgeries, and to induce Plaintiffs to undergo the surgeries without regard to medical necessity and only for the purpose of receiving payment.

740. The misrepresentations and/or concealments were made during Plaintiffs' office visits at Dr. Durrani's CAST offices.

741. Plaintiffs were justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

742. As a direct and proximate result of the aforementioned fraud, Plaintiffs did undergo surgeries which were paid for in whole or in part by their insurance company, and suffered all damages as requested in the prayer for relief.

COUNT VI: SPOLIATION OF EVIDENCE

743. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

744. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

745. Dr. Durrani's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

746. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

747. Dr. Durrani is in fact, the owner of CAST.

748. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiffs.

749. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

750. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

751. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

752. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

753. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiffs, without obtaining proper informed consent thereby causing harm to Plaintiffs.

754. CAST breached its duty to Plaintiffs, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiffs at CAST.

755. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

756. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

757. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: SPOLIATION OF EVIDENCE

758. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

759. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

760. CAST's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

761. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

762. CAST's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

763. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

764. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

765. CAST was fully aware of its actions.

766. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

767. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

768. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

769. CAST's actions were not the result of any bona fide errors.

770. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred.

COUNT IV: FRAUD

771. Upon information and belief, Plaintiffs believe the bills requested by Plaintiffs will indicate that CAST falsely represented that Plaintiffs' surgeries were appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

772. CAST sent out billing to Plaintiffs at their home following their surgery at West Chester Hospital/UC Health and Christ Hospital.

773. The exact dates these medical bills were sent out are reflected in those medical bills.

774. These bills constituted affirmative representations by CAST that the charges related to Plaintiffs' surgery were medically appropriate and properly documented.

775. The bills were sent with the knowledge of CAST that in fact Plaintiffs' surgery was not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health and Christ Hospital associated with Dr. Durrani were not appropriate.

776. The bills sent by CAST to Plaintiffs falsely represented that Plaintiffs' surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

777. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani,

vouching for his surgical abilities, and further was appropriately billing Plaintiffs for CAST's services in association with Dr. Durrani's surgery.

778. As a direct and proximate result of this reliance on the billing of CAST, Plaintiffs incurred medical bills that she otherwise would not have incurred.

779. CAST also either concealed from Plaintiffs facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery, or misrepresented to Plaintiffs the nature of the surgery, and the particular risks that were involved therein.

780. CAST's concealments and misrepresentations regarding Dr. Durrani, Infuse/BMP-2 or Puregen and the nature and risks of Plaintiffs' surgery were material facts.

781. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

782. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiffs at West Chester Hospital/UC Health and Christ Hospital.

783. Plaintiffs were unaware that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs' spine.

784. Had Plaintiffs known before Plaintiffs' surgery that Infuse/BMP-2 or Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgery with Dr. Durrani at West Chester Hospital/UC Health and Christ Hospital.

785. Plaintiffs are still awaiting itemized billing from CAST reflecting the exact totals charged for the use of BMP-2 on the Plaintiffs.

786. As a direct and proximate result of the fraud against Plaintiffs by CAST, Plaintiffs sustained all damages requested in the prayer for relief.

WEST CHESTER HOSPITAL/UC HEALTH COUNTS:

COUNT I: NEGLIGENCE

787. West Chester Hospital/UC Health owed their patient, Plaintiffs, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

788. West Chester Hospital/UC Health acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiffs, including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiffs' surgeries and improper follow up care addressing a patient's concerns.

789. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiffs' surgeries.

790. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of West Chester Hospital/UC Health's knowledge and approval, either knew or should have known the surgery was not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the

violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health.

791. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

792. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiffs constitute medical negligence, lack of informed consent, battery, and fraud.

793. West Chester Hospital/UC Health negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

a. Allowing Dr. Durrani to repeatedly violate the West Chester Hospital/UC Health bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at West Chester Hospital;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by West Chester Hospital staff, doctors, Dr. Durrani's patients and by others;

d. Ignoring information, they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

794. The Safe Medical Device Act required entities such as West Chester Hospital/UC Health to report serious injuries, serious illnesses, and deaths related to failed medical devices to the

FDA and the manufacturer; this was never done.

795. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

796. West Chester Hospital/UC Health sent out billing to Plaintiffs at his home following his surgeries at West Chester Hospital.

797. The exact dates these medical bills were sent out are reflected in those medical bills.

798. These bills constituted affirmative representations by West Chester Hospital/UC Health that the charges related to Plaintiffs' surgeries were medically appropriate and properly documented.

799. The bills were sent with the knowledge of West Chester Hospital/UC Health that in fact Plaintiffs' surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health associated with Dr. Durrani were not appropriate.

800. The bills sent by West Chester Hospital/UC Health to Plaintiffs falsely represented that Plaintiffs' surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

801. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for West Chester Hospital/UC Health's services in association with Dr. Durrani's surgeries.

802. As a direct and proximate result of this reliance on the billing of West Chester Hospital/UC Health, Plaintiffs incurred medical bills that he otherwise would not have incurred.

803. West Chester Hospital/UC Health also either concealed from Plaintiffs facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery, or misrepresented to Plaintiffs the nature of the surgery, and the particular risks that were involved therein.

804. West Chester Hospital/UC Health's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature and risks of Plaintiffs' surgeries were material facts.

805. West Chester Hospital/ UC Health billed Plaintiffs, Christopher Atwood, for "OR ALLOGRAFTS" in the amount of $18,886.58; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 used in Plaintiffs' September 22, 2010, surgery.

806. West Chester Hospital/ UC Health billed Plaintiffs, Rebakah Brady, for "OR ALLOGRAFTS" in the amount of $14,947.20; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 used in Plaintiff's August 27, 2010 surgery.

807. West Chester Hospital/ UC Health billed Plaintiffs, Jennifer Hickey, for "OR ALLOGRAFTS" in the amount of $9,346.51; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 or PureGen used in Plaintiff's November 5, 2010 surgery

808. West Chester Hospital/ UC Health billed Plaintiffs, Paul Marksberry, for "OR ALLOGRAFTS" in the amount of $5,441.20; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's October 4, 2010 surgery.

809. West Chester Hospital/ UC Health billed Plaintiffs, Paul Marksberry, for "OR ALLOGRAFTS" in the amount of $14,978.01; upon information and belief, Plaintiffs believes

that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's November 17, 2010 surgery.

810. Plaintiffs, Robert and Melanie Houghton, are still awaiting itemized billing statements from West Chester Hospital/ UC Health.

811. Plaintiffs, Hiram McCauley, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

812. Plaintiffs, Carol Ross, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

813. Plaintiffs, Mike and Diane Sanders, are still awaiting itemized billing statements from West Chester Hospital/ UC Health.

814. Plaintiffs, David Shempert, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

815. Plaintiffs, Richard Stanfield, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

816. Because of its superior position and professional role as a medical service provider, West Chester Hospital/UC Health had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

817. West Chester Hospital/UC Health intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiffs at West Chester Hospital/UC Health.

818. Plaintiffs were unaware that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs' spine.

819. Had Plaintiffs known before Plaintiffs' surgeries that Infuse/BMP-2 or Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.

820. As a direct and proximate result of the fraud upon Plaintiffs by West Chester Hospital/UC Health, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: SPOLIATION OF EVIDENCE

821. West Chester Hospital/UC Health through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

822. West Chester Hospital/UC Health through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

823. West Chester Hospital/UC Health's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT V: OHIO CONSUMER SALES PROTECTION ACT

824. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

825. West Chester Hospital/UC Health's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

826. West Chester Hospital/UC Health omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

827. West Chester Hospital/UC Health's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

828. West Chester Hospital/UC Health was fully aware of its actions.

829. West Chester Hospital/UC Health was fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's representations at the time West Chester Hospital/UC Health was engaged by Plaintiffs.

830. Had Plaintiffs been aware that West Chester Hospital/UC Health's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

831. West Chester Hospital/UC Health, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

832. West Chester Hospital/UC Health 's actions were not the result of any bona fide errors.

833. As a result of West Chester Hospital/UC Health's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring West Chester Hospital/UC Health restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred.

COUNT VI: AGAINST ALL DEFENDANTS O.R.C. 2923.32 ENGAGING IN A PATTERN OF CORRUPT ACTIVITY; FINES; PENALTIES; FORFEITURE; RECORDS AND REPORTS; THIRD-PARTY CLAIMS TO PROPERTY SUBJECT TO FORFEITURE (State RICO)

834. **Plaintiffs adopt and incorporate herein by reference each and every allegation in this Complaint as detailed to support the pattern of corrupt activity including regarding BMP-2 and PureGen.**

835. Pursuant to, O.R.C 2923.32 (A).

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
>
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
>
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.
>
> A purchase of securities on the open market with intent to make an investment, without intent to control or participate in the control of

> the issuer, and without intent to assist another to do so is not a violation of this division, if the securities of the issuer held after the purchase by the purchaser, the members of the purchaser's immediate family, and the purchaser's or the immediate family members' accomplices in any pattern of corrupt activity or the collection of an unlawful debt do not aggregate one per cent of the outstanding securities of any one class of the issuer and do not confer, in law or in fact, the power to elect one or more directors of the issuer.
>
> Ohio Rev. Code Ann. § 2923.32 (West)

836. The Ohio Revised Code goes on to state that "Person," is defined as, "(G) "Person" means any person, as defined in section 1.59 of the Revised Code, and any governmental officer, employee, or entity." Ohio Rev. Code Ann. § 2923.31 (West)

837. West Chester Hospital, LLC (hereinafter "West Chester Hospital",) was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

838. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

839. West Chester Hospital/ UC Health would be considered an entity and according to the Ohio Revised Code definition of a person

840. The Ohio Revised Code also states that,

> (C) "Enterprise" includes any individual, sole proprietorship, partnership, limited partnership, corporation, trust, union, government agency, or other legal entity, or any organization, association, or group of persons associated in fact although not a legal entity. "Enterprise" includes illicit as well as licit enterprises.
>
> Ohio Rev. Code Ann. § 2923.31 (West)

841. The Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

842. Dr. Durrani was the sole owner of CAST and was directly associated with CAST.

843. CAST is an enterprise.

844. West Chester Hospital/ UC Health suspended Dr. Durrani privileges on August 6, 2010.

845. Dr. Durrani continued to see new clients and/ or perform unnecessary surgeries, even though he was under suspension, including those of Plaintiffs.

846. West Chester Hospital/ UC Health had knowledge that Dr. Durrani was performing surgeries while under suspension.

847. West Chester Hospital/ UC Health had knowledge that Dr. Durrani was categorizing the unnecessary surgeries as "emergencies," and West Chester Hospital/UC Health allowed the surgeries to continue. West Chester Hospital/ UC Health billed for these fraudulent surgeries and aided and conspired with CAST and Dr. Durrani to achieve these acts.

848. Dr. Durrani was on suspension for incomplete charts, medical records and late dictations of his surgeries, yet, West Chester Hospital/ UC Health allowed for Dr. Durrani to perform more unnecessary surgeries and then billed Plaintiffs for those surgeries.

849. Dr. Durrani would see Plaintiffs at his CAST offices.

850. Dr. Durrani would tell Plaintiffs that without surgery, immediately, they would suffer paralysis or death. Plaintiffs would then have the surgery.

851. CAST would schedule the surgery with West Chester Hospital/ UC Health.

852. West Chester Hospital/ UC Health would then allow Dr. Durrani to perform, the unnecessary, surgery on the Plaintiffs and West Chester Hospital/ UC Health would then bill for those unnecessary surgeries.

853. West Chester Hospital/ UC Health allowed for and participated in the fraudulent billing practices, assault due to the unnecessary surgeries, and conspired to aid CAST and Dr. Durrani in these corrupt activities.

854. West Chester Hospital/ UC Health profited from Dr. Durrani's unnecessary surgeries and West Chester Hospital/UC Health billed Plaintiffs for the unnecessary surgeries, even though Dr. Durrani was under suspension and was not allowed to see new patients and/or perform surgeries.

855. West Chester through the fraudulent billing practices and collected unlawful debt collection, from unnecessary surgeries, had an interest in helping CAST continue to lure Plaintiffs into unnecessary surgeries and allow the unnecessary surgeries to occur, even though Dr. Durrani was under suspension. This corrupt practice started in May 2009 through at least September 2013, for the purpose of these particular Plaintiffs.

856. West Chester Hospital/ UC Health, billed Plaintiffs for the unnecessary surgeries, and used the proceeds in the operation of the enterprises.

857. The Defendants as detailed in this entire Complaint herein engaged in a criminal enterprise through a pattern of corrupt activity and the collection of an unlawful debt.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;

4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of their injuries;
10. The damages to their credit as a result of their injuries;
11. Punitive damages;
12. Costs;
13. Attorneys' fees;
14. Interest;
15. All property loss;
16. All other relief to which they are entitled including O.R.C. 1345.01
17. All relief under O.R.C. 2923.32. Based upon 1-16 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,

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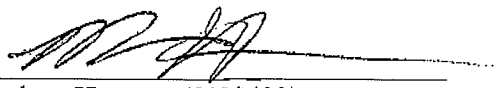
JURY DEMAND

Plaintiffs make a demand for a jury under all claims.



Matthew Hammer (0092483)
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